UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| UNITED STATES OF AMERICA | * | |
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| v. | * | 1:15-cr-10076-ADB |
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| WILLIAM FACTEAU and PATRICK FABIAN, | * | |
| | * | |
| | * | |
| Defendants. | * | |

**MEMORANDUM AND ORDER**

**(Motions to Dismiss, Motions to Sever, Objections to Magistrate Judge's Orders)**

BURROUGHS, D.J.

On April 8, 2015, a grand jury returned an eighteen-count Indictment against Defendants William Facteau ("Facteau") and Patrick Fabian ("Fabian"). All of the charges in the Indictment related to the sale of a medical device known as the Relieva Stratus Microflow Spacer ("Stratus"), which was sold by Acclarent, Inc. ("Acclarent"), the Defendants' former employer. Although Acclarent sought and received approval from the United States Food and Drug Administration ("FDA"), through the 510(k) process, to market and sell Stratus for use as a "sinus spacer," the Indictment alleges that the Stratus was not actually designed, sold, or intended to be used for that purpose. Instead, Acclarent, under Defendants' leadership, allegedly designed and sold the Stratus as a steroid-delivery device, which was not a use approved by the FDA. The Indictment further alleged that by misrepresenting Acclarent's true intended use and seeking approval through the abbreviated 510(k) process, rather than through a new device application, and by selling the Stratus for off-label use, Defendants were engaged in a scheme to deceive not only the FDA, but also potential and actual purchasers of Acclarent stock.

Defendants' alleged goal was to inflate the value of Acclarent through off-label promotion and thereby enrich themselves through larger stock options and bonuses. The Indictment charged Defendants with:

- one count of conspiracy to commit securities fraud and the offenses of adulteration and misbranding, in violation of 18 U.S.C. § 371 (Count 1);
- three counts of securities fraud in violation of 15 U.S.C. §§ 78j(b), 78ff(a) and 17 C.F.R. § 240.10b-5 (Counts 2, 3, and 4);
- four counts of wire fraud and attempted wire fraud in violation of 18 U.S.C. §§ 1343, 1349 (Counts 5, 6, 7, and 8);
- five counts of introducing an adulterated device into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a) (1)-(2), 351(f)(1)(B) (Counts 9, 10, 11, 12 and 13); and
- five counts of introducing a misbranded device into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a) (1)-(2), 352(a), 352(f), 352(o) (Counts 14, 15, 16, 17, and 18).

See ECF No. 1 (hereinafter, "Indictment").

Prior to trial, the Defendants filed seven motions to dismiss the Indictment, in which they argued that all eighteen counts of the Indictment should have been dismissed on various legal grounds. [ECF Nos. 183, 184, 186, 187, 190, 193, 195]. The government filed a consolidated Opposition to these motions [ECF No. 224], and the Defendants filed Replies corresponding to their original motions [ECF Nos. 234, 235, 237, 238, 239, 240, 241]. The Court held hearings on the motions to dismiss on February 4 and 5, 2016.

Each defendant also filed a motion to sever their trials from one another. [ECF Nos. 214, 219], as well as Objections to Magistrate Judge Cabell's Order denying Defendants' Motion to Compel Discovery [ECF No. 167], and Objections to Magistrate Judge Cabell's Order denying Defendants' Motion to Compel Disclosure of the Government's Legal Instructions to the Grand Jury [ECF No. 165].

Prior to trial, (1) Defendants' Motions to Sever were denied without prejudice to renew; (2) Defendants' Objections to Magistrate Judge Cabell's Orders were overruled; and (3)

Defendants' Motions to Dismiss were denied without prejudice to renew. Although all of these motions were ruled on orally from the bench, and while some of the issues presented by the motions are now moot,[1] the Court is nonetheless providing this written explanation of its previous rulings.

The Court notes that at the time these motions were decided, all facts set forth in the Indictment were accepted as true. Given the fact that the case has now been tried to verdict, the Court will not summarize these facts except as relevant to the disposition of each motion.

## I. DEFENDANTS' MOTIONS FOR SEVERANCE

Both Defendants filed motions to sever their trials from one another [ECF Nos. 214, 219], arguing that a joint trial would unduly prejudice their respective rights.

Federal Rule of Criminal Procedure 8(b) provides that an indictment "may charge 2 or more defendants if they are alleged to have participated in the same act or transaction, or in the same series of acts or transactions, constituting an offense or offenses." Fed. R. Crim. P. 8(b). The "general rule" is that two defendants indicted together should be tried together, in order "to prevent inconsistent verdicts and to conserve judicial and prosecutorial resources." United States v. Soto-Beniquez, 356 F.3d 1, 29 (1st Cir. 2003); see also Zafiro v. United States, 506 U.S. 534, 537 (1993). The preference for a joint trial is "particularly strong" where, as here, there is a conspiracy charge. United States v. Saunders, 553 F.3d 81, 85 (1st Cir. 2009).

[1] Shortly before the trial began, the government voluntarily dismissed all of the securities fraud charges in Counts 2-4 (the "securities counts") and one of the wire fraud charges in Count 8. The case was tried to a jury in a 30 day trial in June and July 2016. The jury returned its verdict on July 20, 2016 after approximately two and a half days of deliberations. The jury acquitted the Defendants on Count 1 (conspiracy), and Counts 5-7 (wire fraud). In addition, although the jury acquitted the Defendants of the felony adulteration and misbranding offenses charged in Counts 9-18, they convicted both Defendants on all of the misdemeanor adulteration and misbranding offenses charged in Counts 9-18.

Although neither Defendant argued that Rule 8(b) joinder was improper in this case, both argued that the Court should, nonetheless, have exercised its discretion to sever their trials pursuant to Rule 14(a) of the Federal Rules of Criminal Procedure. Rule 14(a) provides that the court may sever the defendants' trials if a consolidated trial "appears to prejudice a defendant or the government." Fed. R. Crim. P. 14(a). When defendants have been properly joined under Rule 8(b), the court should grant a severance motion "only if there is a serious risk that a joint trial would compromise a specific trial right of one of the defendants, or prevent the jury from making a reliable judgment about guilt or innocence." Zafiro, 506 U.S. at 539.

Defendants argued that severance was warranted for a number of reasons, including the potential for "evidentiary spillover," such that evidence properly admissible against only one of the two Defendants might, nonetheless, unfairly prejudice the other. See id. Defendants pointed out that they held different leadership positions within the company's management team, had different job responsibilities, and that Mr. Fabian's period of employment at Acclarent did not entirely overlap with that of Mr. Facteau. Thus, they speculated that some of the evidence admissible as to one defendant may not have been admissible against the other. The Court did not find those circumstances to warrant severance. "There is always some prejudice in any trial where more than one offense or offender are tried together—but such 'garden variety' prejudice, in and of itself, will not suffice." United States v. Boylan, 898 F.2d 230, 246 (1st Cir. 1990). Further, even assuming that some spillover might occur, the court found that any potential risk of prejudice could be adequately mitigated by limiting instructions to the jury. See Zafiro, 506 U.S. at 539. Similarly, potential differences in trial strategies, barring unusual circumstances not seemingly present here, were not expected to create an undue risk of prejudice, and the Court determined that any potential prejudice could be managed by limiting instructions. Although

each Defendant may have believed that he had a significantly better chance of acquittal if tried alone, "it is well settled that defendants are not entitled to severance merely because they may have a better chance of acquittal in separate trials." Id. at 540.

In sum, the Court did not find that severance was warranted. Although the Court initially denied the severance motions without prejudice to renewing them prior to trial, neither Defendant renewed his motion.

## II. DEFENDANTS' OBJECTIONS TO MAGISTRATE JUDGE'S RULINGS ON MOTIONS TO COMPEL

On April 8, 2015, the Court referred this criminal case to Magistrate Judge Cabell for full pretrial proceedings, pursuant to Fed. R. Crim. P. 59(a) and 28 U.S.C. § 636(b)(1)(A). Accordingly, the Magistrate Judge issued rulings on all of the parties' non-dispositive, pretrial discovery motions. Defendants filed objections to two of his rulings. See Fed. R. Crim. P. 59(a) (setting forth procedure for raising objections to order of magistrate judge).

First, Defendants objected to the Magistrate Judge's October 28, 2015 Order [ECF No. 153] denying in part Defendants' Motion to Compel Discovery [ECF No. 83]. Specifically, Defendants objected to the portion of the Order that declined to compel the production – in their entirety – of two letters written to the Department of Justice by counsel for Ethicon, Inc., and its parent company, Johnson & Johnson, Inc. (the "J&J Letters"). Although the government had disclosed portions of the J&J Letters to Defendants, and although the Magistrate Judge subsequently ordered the government to produce additional excerpts, he allowed the government to withhold other information contained within the letters on the ground that the unproduced portions of the letters were not exculpatory or material.

Second, Defendants objected to the portion of the Magistrate Judge's October 29, 2015 Order [ECF No. 154] that denied Defendants' Motion to Compel Disclosure of the

Government's Legal Instructions to the Grand Jury. [ECF No. 84]. According to the Defendants, the Indictment strongly suggested the grand jury was "misinstructed on the applicable law," particularly with regard to the wire fraud charges in Counts 5-7, and the adulteration and misbranding charges in Counts 9-13. Defendants further contended that disclosure of the legal instructions to the grand jury – or, at the very least, *in camera* review of the instructions by the Court – was necessary to "determine the extent to which the grand jury was misinstructed as to the operative law," and whether these errors warranted the dismissal of any counts alleged in the Indictment.

**A. Legal Standard**

Federal Rule of Criminal Procedure 59(a) provides that the district court must "consider timely objections and modify or set aside any part of the [magistrate judge's] order that is contrary to law or clearly erroneous." Fed. R. Crim. P. 59(a); see also United States v. Garcia, 983 F.2d 1160, 1166 (1st Cir. 1993) ("A magistrate's discovery order may be set aside where the order is clearly erroneous or contrary to law.") The "clearly erroneous" standard, which applies to any factual findings made by the magistrate judge, cf. Phinney v. Wentworth Douglas Hosp., 199 F.3d 1, 4 (1st Cir. 1999); see also United States v. Gioia, 853 F. Supp. 21, 26 n.3 (D. Mass. 1994), means that the Court "must accept both the trier's findings of fact and the conclusions drawn therefrom unless, after scrutinizing the entire record, [the Court] 'form[s] a strong, unyielding belief that a mistake has been made.'" Phinney, 199 F.3d at 4 (quoting Cumpiano v. Banco Santander, P.R., 902 F.2d 148, 152 (1st Cir. 1990)) (alterations added). "While the First Circuit has not discussed the meaning of 'contrary to law,' other courts have found that an order is contrary to law when it fails to apply or misapplies relevant statutes, case law, or rules of

procedure." United States v. Gorski, 36 F. Supp. 3d 256, 264 (D. Mass. 2014) (collecting cases) (internal quotations and citation omitted).

**B. Discussion**

**i. J&J Letters**

In considering the Defendants' Objections to Magistrate Judge's Order Denying Defendants' Motion for Production of Legal Instructions to the Grand Jury [ECF No. 84], this Court, like the Magistrate Judge, reviewed the J&J Letters *in camera*. To be cautious, the government also provided the Court with several powerpoint presentations for similar *in camera* review. Although the government had not produced the powerpoint presentations to the Defendants, it represented to the Court that it had produced all of the documents excerpted in the presentations. After reviewing the J&J Letters and the presentations, this Court determined that there was nothing material or exculpatory in the presentation slides that would not have been produced to the defense via the excerpted documents, which the government represented had already been produced. The Court identified one sentence or partial sentence in each of the J&J Letters that the Court believed contained factual material information. At the hearing on March 15, 2016, the government voluntarily agreed to produce those two additional excerpts from the J&J Letters to the Defendants. In light of these supplemental disclosures, and based on the Court's own review of the J&J letters and the additional powerpoint presentations that were not before the Magistrate Judge, the Court OVERRULED the remainder of Defendants' Objections to the Magistrate Judge's October 28, 2015 Order. [ECF No. 153].

**ii. Grand Jury Instructions**

On October 29, 2015, the Magistrate Judge entered an Order denying Defendants' Motion for Production of Legal Instructions To The Grand Jury, in which he found that "Defendants have not demonstrated a particularized need for the Government's legal instructions

to the grand jury." [ECF No. 154]. In so holding, however, he also noted that because "this dispute at its core is a dispute about what is the correct interpretation of applicable law"…."this issue may be more appropriately and more fully explored in the context of a dispositive Rule 12 motion before the trial judge." Id.

Upon review, the Court found this to be a difficult issue. On the one hand, Rule 6(e) of the Federal Rules of Criminal Procedure imposes an absolute obligation of secrecy regarding grand jury proceedings, with some very limited exceptions. One of these exceptions provides that the court "may authorize disclosure . . . of a grand jury matter . . . at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury." Fed. R. Crim. P. 6(e)(3)(E)(ii).

In addition to the text of the Rule itself, the case law also supports a commitment to keeping grand jury proceedings secret. See, e.g., Douglas Oil Co. v. Petrol Stops N.W., 441 U.S. 211, 218 (1979) ("We have consistently recognized that the proper functioning of our grand jury system depends upon the secrecy of grand jury proceedings."); United States v. McMahon, 938 F.2d 1501, 1504 (1st Cir. 1991) ("The Supreme Court has repeatedly has recognized the importance of secrecy in grand jury proceedings even after . . . the grand jury has concluded its function.") (citing Douglas Oil, 441 U.S. at 222). The reasons for preserving grand jury secrecy include the following:

> First, if preindictment proceedings were made public, many prospective witnesses would be hesitant to come forward voluntarily, knowing that those against whom they testify would be aware of that testimony. Moreover, witnesses who appeared before the grand jury would be less likely to testify fully and frankly, as they would be open to retribution as well as to inducements. There also would be the risk that those about to be indicted would flee, or would try to influence individual grand jurors to vote against indictment. Finally, by preserving the secrecy of the proceedings,

> we assure that persons who are accused but exonerated by the grand jury will not be held up to public ridicule.

Douglas Oil, 441 U.S. at 219. "Parties seeking grand jury transcripts under Rule 6 (e) must show that the material they seek is needed to avoid a possible injustice in another judicial proceeding, that the need for disclosure is greater than the need for continued secrecy, and that their request is structured to cover only material so needed." Id. at 222.

In the instant case, however, the Defendants only sought access to or review of the legal instructions that the prosecutors provided to the grand jurors prior to asking them to return an indictment. Legal instructions provided by prosecutors do not implicate any of the concerns typically cited in support of grand jury secrecy. Although it is clear that disclosure of grand jury materials is disfavored, "[i]t is equally clear that as the considerations justifying secrecy become less relevant, a party asserting a need for grand jury transcripts will have a lesser burden in showing justification. Id. at 223. Further, the Supreme Court has emphasized "that a court called upon to determine whether grand jury transcripts should be released necessarily is infused with substantial discretion." Id.

In the instant case, the Court ultimately declined to review or compel disclosure of the grand jury instructions. Because this motion is now largely moot, the Court will not undertake a prolonged review of the issue. Suffice it to say that the case law did not easily permit the Court to find that the Magistrate Judge's ruling on the issue was "clearly erroneous," based both on the standard of review and the merits of the issue.

That being said, the Court sees no reason why the prosecutors' instructions to the grand jury should be kept secret. What a prosecutor says to the grand jurors before asking them to return an indictment does not compromise the interests sought to be protected by grand jury secrecy. Further, allowing the instructions to be disclosed through the discovery process would

help ensure the integrity of the grand jury process, incentivize prosecutors to be careful in instructing a grand jury, and give some teeth to the grand jury's "shield" function. See United States v. Mandujano, 425 U.S. 564, 573 (1976). It would also alert defense counsel to the possibility of an irregularity that could warrant a review of the grand jury process in a particular case. Given the length of time that it takes a case to get to trial, the stigma and harm done to a defendant simply by virtue of being indicted, even if later acquitted, and the largely unfettered power of the grand jury, the small step of allowing a defendant some visibility into the legal instructions given to the grand jury would help protect the defendant's rights, while fully maintaining the secrecy that is so fundamental to the functioning of our grand jury system. Nonetheless, given the circumstances of this case and the prevailing case law, this motion was denied.

## III. DEFENDANTS' MOTIONS TO DISMISS

### A. Legal Standard

"An indictment is legally sufficient if it first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and, second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense." United States v. Laureano-Perez, 797 F.3d 45, 60 (1st Cir. 2015) (internal quotations and citations omitted); see also Fed. R. Crim. P. 7(c). Although an indictment must contain a "plain, concise and definite written statement of the essential facts constituting the offense charged," and "should be specific enough to notify the defendant of the nature of the accusation against him and to apprise the court of the facts alleged," United States v. Berk, 652 F.3d 132, 137-38 (1st Cir. 2011) (internal quotations and citations omitted), the government "need not put forth specific evidence to survive a motion to dismiss." United States v. Ngige, 780 F.3d 497, 502 (1st Cir. 2015) (citing United States v. Stewart, 744 F.3d 17, 21 (1st Cir. 2014)). "When a

defendant seeks dismissal of an indictment, courts take the facts alleged in the indictment as true, mindful that 'the question is not whether the government has presented enough evidence to support the charge, but solely whether the allegations in the indictment are sufficient to apprise the defendant of the charged offense.'" Ngige, 780 F.3d at 502 (quoting United States v. Savarese, 686 F.3d 1, 7 (1st Cir. 2012)).

By the Court's count, Defendants' seven motions to dismiss raised at least ten separate challenges to the charges alleged in the Indictment. The vast majority of these motions, however, did not challenge the sufficiency of the facts alleged in the Indictment, but rather the legal viability of the government's charging theories. Furthermore, many of Defendants' motions attacked only certain portions of the government's purported charging theories. Although Defendants contended that the legally unsustainable theories were inseparable from any viable ones, and thus irrevocably infected the Indictment, the Court rejected that proposition as a general matter. While an indictment can be dismissed for failure to charge an offense, see United States v. Ochs, 842 F.2d 515, 527-28 (1st Cir. 1988), the presence of a legally defective theory is not necessarily fatal, if the indictment contains another independent and legally sufficient ground to sustain the charges. See id.; see also United States v. Doherty, 867 F.2d 47, 55-56 (1st Cir. 1989). The Court evaluated Defendants' motions to dismiss with these principles in mind.

**B. Discussion**

The Defendants' seven motions to dismiss included the following:

1. Motion to Dismiss, in part, Counts One (A), Five through Seven, and Nine through Eighteen of the Indictment Because, as a Matter of Law, Stratus Lawfully Received and Maintained FDA Clearance [ECF No. 183] ("MTD 1");

2. Motion to Dismiss the Indictment Because the Adulteration and Misbranding Charges are Legally Deficient and Violate the Constitution [ECF No. 184] ("MTD 2");

3. Motion to Dismiss the Indictment for Lack of Due Process [ECF No. 186] ("MTD 3")

4. Motion to Dismiss the Wire Fraud Counts (Including Count Eight) for Additional Legal Deficiencies [ECF No. 187] ("MTD 4");

5. Motion to Dismiss the Securities Fraud Counts for Failure to State an Offense and Multiplicity [ECF No. 190] ("MTD 5");

6. Motion to Dismiss the Strict-Liability Misdemeanors Charged in Counts Nine Through Eighteen of the Indictment for Unconstitutional Vagueness [ECF No. 193] ("MTD 6"); and

7. Motion to Dismiss Counts 1 and 14-18 of the Indictment as Regards Sec. 352(f)(1) [ECF No. 195] ("MTD 7")

MTD 4 challenged the wire fraud counts; MTD 5 challenged the securities fraud counts, and the remaining motions to dismiss all pertained primarily to the adulteration and misbranding charges.

**i. MTD 5: The Securities Fraud Counts (2-4)**

The securities fraud charges in Counts 2-4 were premised on allegedly false and misleading statements and omissions made in connection with the sale of Acclarent to a company known as Ethicon.

In the fall of 2009, Acclarent entered into merger discussions with Ethicon, a corporation headquartered in New Jersey. See Indictment ¶ 84. During these discussions, Defendants did not disclose to Ethicon that Acclarent and its sales force had been selling the Stratus for off-label use, specifically for steroid delivery. Id. ¶¶ 85-86. These omissions were alleged to be material to Ethicon's ultimate decision, in December 2009, to purchase Acclarent's stock for $787 million. Id. ¶¶ 87-88. Further, Facteau was alleged to have made false statements in the Merger Agreement between Ethicon and Acclarent, including that the company held all required FDA clearances and approvals that were material to operating Acclarent's business, and that the company was and at all times had been in compliance with those clearances and approvals. Id. ¶¶

89-90. The Indictment also alleged that Facteau falsely represented that the operation of Acclarent's business, including the labeling, marketing, and distribution of all Acclarent's products, was and at all times had been in material compliance with all applicable "Legal Requirements, Company Permits, Governmental Entities and ordered administered by the FDA." Id. ¶ 91. These representations were also alleged to be material to Ethicon's decision to purchase Acclarent. Id. ¶ 92.

The Merger Agreement provided that approximately $109 million (roughly one-seventh of the total purchase price) would be held in escrow for one to two years following the merger, in order to indemnify Ethicon for any possible breach of the Agreement or false representations made therein. Id. ¶ 93. Eventually, over the two year period following the merger, Ethicon released the escrow amounts, which were paid out to former Acclarent shareholders, including Defendants. Id. ¶ 95.

Thus, the Indictment alleges that Defendants both made and caused to be made false and fraudulent statements and material omissions to Ethicon and others regarding the design, purpose, and intended use of the Stratus, the past and ongoing promotion of Stratus, and Acclarent's compliance with the law, all with the intent of making Acclarent look like a more desirable target company, and of maximizing the payments received from Ethicon under the merger. Id. ¶ 96.

Count 2 of the Indictment was predicated on the January 2010 sale of stock from Acclarent to Ethicon. Counts 3 and 4 were based on the two later escrow payments. In MTD 5, Defendants moved to dismiss Counts 3 and 4 for failing to state offenses for securities fraud, and for being multiplicious of Count 2. They also move to dismiss Counts 2, 3 and 4 for failing to allege actionable "scheme liability" under Rule 10b-5(a) and (c).

Defendants asserted that there was only one sale of securities (*i.e.*, the January 2010 stock purchase), and that the claims in Count 3 and 4 were therefore either not "in connection with" a sale of securities or were multiplicious of Count 2. The resolution of this issue depended on whether the two escrow payments were independently actionable events that could support a securities fraud allegation. In sum, if the escrow payments could not support separate counts, then Counts 3 and 4 were either multiplicious of Count 2 or failed to state a claim.

In order to resolve the issue, it would have been necessary to determine the proper unit of prosecution – meaning whether there was only a single sale of stock or if the subsequent escrow payments were sufficiently related to that sale to support additional counts of the Indictment. As discussed at the hearing, the case law on this issue is unclear. See, e.g., U.S. v. Langford, 946 F.2d 798, 804 (11th Cir. 1991) ("To avoid the vices of multiplicity in securities fraud cases, each count of the indictment must be based on a separate purchase or sale of securities and each count must specify a false statement of material fact . . . in connection with that purchase or sale."); Peoria Union Stock Yards Co. Ret. Plan v. Penn Mut. Life Ins. Co., 698 F.2d 320, 326 (7th Cir. 1983) (where contract was a continuing one that required periodic payments, fraudulent statements to keep contributions coming "was fraud in connection with the continuing sale of a security"); Goodman v. Epstein, 582 F.2d 388, 414 (7th Cir. 1978) (holding that if "an investment decision remained to be made," at the time of the alleged non-disclosure, then nondisclosure would be "in connection with the purchase of a security"). In this case, the proper unit of prosecution was a mixed question of law and fact that was not determinable without further factual details about the nature of the initial stock sale and the subsequent escrow payments.

Otherwise, the Court determined that Counts 3 and 4 were legally sufficient, in that they recited the elements of the offenses charged, fairly informed the Defendants of the nature of the charges, and provided sufficient information to guard against successive prosecutions for these same offenses. Therefore, this Motion to Dismiss was denied with leave to renew at the close of the government's case, if the evidence adduced at trial established that there was only one actionable securities transaction.

Once the government elected to dismiss the securities counts prior to trial, however, these issues became moot.

**ii. MTD 4: The Wire Fraud Counts (Counts 5-8)**

In MTD 4, the Defendants moved to dismiss the wire fraud counts in whole or part on several legal grounds, each of which is addressed below.

The Indictment charged two theories of wire fraud. First, Counts 5, 6, and 7 alleged that Defendants engaged in a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, "to wit, to sell Stratus as a steroid delivery device, an intended use not cleared or approved by the FDA, and hiding that conduct *from the FDA and actual and potential investors and purchasers of Acclarent*, all in order to increase the revenues and valuation of Acclarent, and their own stock options and compensation." Indictment ¶ 138 (emphasis added). In Count 8 (which the government voluntarily dismissed prior to trial), the Indictment recited similar allegations regarding Defendants' "scheme or artifice to defraud," except that instead of "hiding that conduct from the FDA and actual and potential investors," Defendants were alleged to have hidden their conduct "from the FDA and Ethicon," and that they did so "contrary to Ethicon's direction and their representations to Ethicon, all in order to

receive and increase the revenues of Acclarent, and their own compensation and bonuses." Id. ¶ 140.

First, Defendants argue that the "fraud on FDA and actual and potential investors" theory in Counts 5-7 failed to state an offense, because the Indictment did not identify any "actual and potential investors and purchasers" of Acclarent, besides Ethicon. [MTD 4, p. 12]. At oral argument, the parties agreed that the government would provide a bill of particulars identifying any other "potential" investors referenced in Counts V-VII. Accordingly, Defendants' Motion to Dismiss was DENIED AS MOOT on this issue.

Second, Defendants argued that Counts 5-7 had to be dismissed to the extent they alleged that Defendants mislead the FDA *in order to obtain and maintain 510(k) clearance for Stratus* and thereby increase Acclarent's revenues and valuation, as well as their own compensation. Citing Cleveland v. United States, 531 U.S. 12, 26 (2000), Defendants argued that obtaining or maintaining regulatory approval to market a device could not qualify as a "deprivation of money or property" under the wire fraud statute. Although the Court agreed that this was an accurate statement of law, it became clear through briefing and oral argument that the government did not intend to prove that regulatory approval was the object of Defendants' alleged scheme. Instead, they intended to prove that Defendants devised a scheme to deceive the FDA and others, in order to obtain money or property from others – not to obtain anything regulatory clearance from the FDA. This approach appeared to be permissible under First Circuit law. See United States v. Christopher, 142 F.3d 46, 54 (1st Cir. 1998) ("Nothing in the mail and wire fraud statutes requires that the party deprived of money or property be the same party who is actually deceived."). Therefore, Defendants' Motion to Dismiss the Indictment was DENIED on this point.

Third, Defendants argued that the Court should dismiss the wire fraud counts to the extent that they were based on allegedly fraudulent statements or omissions regarding the Stratus' "intended use" in Acclarent's 510(k) submissions to the FDA. According to Defendants, any such misrepresentations or omissions in the 510(k) itself could not have influenced the FDA's determination that the Stratus was substantially equivalent to predicate spacer devices, because the Food and Drug Administration Modernization Act of 1997 (the "Modernization Act") prohibited the FDA from considering any other potential use of the device, other than the intended use presented in the 510(k) notification.

Specifically, the Modernization Act amended Section 513 of the Food, Drug, and Cosmetic Act to provide that when the FDA evaluates whether a proposed device is "substantially equivalent" to a predicate device for purposes of 510(k) clearance, "[a]ny determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under Section 360(k) of this title." 21 U.S.C. § 360c(i)(1)(E)(i); see Pub. L. No. 105-115, § 205(b), 111 Stat. 2337 (1997) (codified as amended at 21 U.S.C. § 360c(i)(1)(E)(i)). In other words, the FDA must decide substantial equivalence – and thus approve or deny the 510(k) – based on the intended use set forth in the device's proposed labeling. Accordingly, Defendants argued that even assuming that the "intended use" that Acclarent set forth in the 510(k) notification did not reflect the Company's true intentions with respect to the Stratus, and/or omitted to include the use actually intended by the Company, those alleged misrepresentations or omissions were immaterial to the FDA's decision to grant 510(k) clearance, as the FDA could not have considered other potential uses, even if they had been disclosed. See United States v. Appolon, 715 F.3d 362, 368 (1st Cir. 2013) ("A material statement 'has a natural tendency to influence, or [is] capable of influencing, the decision of the

decisionmaking body to which it was addressed.'") (quoting Neder v. United States, 527 U.S. 1, 16 (1999)).

If the wire fraud alleged in the Indictment were narrowly limited to a scheme to defraud the FDA into approving Acclarent's 510(k) notification and thereby obtain regulatory approval, Defendants' materiality arguments might have prevailed. The wire fraud scheme actually alleged, however, was considerably broader. The Indictment charged that Defendants' alleged scheme and artifice to defraud was to "sell Stratus as a steroid delivery device, an intended use not cleared or approved by the FDA, and hiding that conduct from the FDA and actual and potential investors . . . all in order to increase the revenues and valuation of Acclarent, and their own stock options and compensation . . . ." Indictment ¶ 138. First, the alleged object of the wire fraud was not to obtain regulatory approval. Second, the FDA was not the only party that was allegedly deceived by Defendants' conduct. See also Indictment ¶ 118. Third, these alleged misrepresentations and omissions may have had the capacity to influence the FDA in other ways, even assuming that they were not material – strictly speaking – to the FDA's decision to clear Stratus for use as a sinus spacer via the 510(k) process. Therefore, Defendants' Motion to Dismiss on this ground was DENIED without prejudice to renew at trial, if the government failed to present evidence that the statements or omissions contained in the 510(k) notification were material.

Fourth, Defendants contended that the "fraud on FDA and Ethicon" theory in Count 8 failed to adequately allege that Defendants intended to deprive Ethicon of money or property. Specifically, they noted that one alleged object of Defendants' purported scheme was to increase their own compensation or bonuses, and they argued that the government had improperly attempted to bring charges of honest services fraud under the guise of a wire fraud charge.

Historically, prosecutors used mail and wire fraud statutes as a "broad shield," protecting people from "schemes to deprive them of intangible, as well as tangible, property." United States v. Grandmaison, 77 F.3d 555, 565 (1st Cir. 1996) (regarding mail fraud statute) (internal quotations and citation omitted). Accordingly, an employee could be prosecuted for mail or wire fraud under the theory that the "property" of which the employer was deprived was its right to the employee's honest services. In 1987, however, the United States Supreme Court held in McNally v. United States that the mail fraud statute "did not embrace intangible rights," and that the statute did not "prohibit schemes to defraud individuals of their intangible rights to the honest services of government." Grandmaison, 77 F.3d at 565-66 (citing McNally, 483 U.S. 350, 359-60 (1987)). Instead, the Court held that the mail fraud statute was limited in scope to the protection of property rights. McNally, 483 U.S. at 360. Thus, the question presented was whether the revenues, compensation and bonuses referred to in Count 8 of the Indictment are property covered by the wire fraud statute, or whether they are a form of honest services fraud barred by McNally.

The government contended that McNally posed no bar to the "fraud on the FDA and Ethicon" wire fraud theory charged in Count 8, arguing that the Indictment charged Defendants with engaging in a fraudulent scheme, the goal of which was to obtain "money or property" in the form of: (1) positions and accompanying salaries in the new-Ethicon-owned Acclarent; and (2) increased compensation in the form of bonuses and other payments tied to sales and/or revenue targets.

With respect to obtaining "positions and accompanying salaries in the new Ethicon-owned Acclarent," such allegations were not charged anywhere in the Indictment. Instead, the Indictment alleged that Defendants' alleged scheme was carried out to "receive and increase the

revenues of Acclarent, and their own compensation and bonuses." Indictment ¶ 140. Because nothing in the Indictment suggested that the grand jury indicted Defendants on this theory of wire fraud, the Court held that the government could not proceed with this theory at trial.

A closer question was whether the government could have based its wire fraud charge in Count 8 upon "increased compensation in the form of bonuses and other payments." Although the concept of "property" is to be interpreted broadly, see McNally, 483 U.S. at 356, the Court was cognizant of not "let[ting] in through the back door the very prosecution theory that the Supreme Court tossed out the front" in McNally. Ochs, 842 F.2d at 527. After reviewing the case law in this Circuit, the Court concluded that while the mere maintenance of a preexisting salary or employment did not satisfy the "money or property" requirement of the wire fraud statute, obtaining a new position, an increase in salary, or the payment of a bonus could be sufficient, as long as those benefits were obtained through the fraudulent scheme, and the defendant was not otherwise entitled to receive those benefits. Compare United States v. Doherty, 867 F.2d 47, 56 (1st Cir. 1989) (holding that indictment was valid, where allegations made it "clear that the conspirators were after money, by obtaining promotions and raises *through fraud*") (emphasis added) and United States v. Allard, 864 F.2d 248, 251 (1st Cir. 1989) (upholding indictment charging defendant with mail fraud, on the grounds that he devised a fraudulent scheme to obtain a medical license, and thereby obtain remunerative payments from hospital); with United States v. Billmyer, No. CRIM. 94-29-01-JD, 1995 WL 54471, at *9 (D.N.H. Feb. 3, 1995) (holding that indictment failed to charge defendants with the crime of wire fraud, where it merely alleged that the employees "continued to accrue" salary despite their dishonest acts), aff'd sub nom. United States v. Josleyn, 99 F.3d 1182 (1st Cir. 1996).

Here, the Indictment charged that the Defendants' allegedly fraudulent scheme was undertaken to "receive and increase the revenues of Acclarent, and their own compensation and bonuses." Indictment ¶ 140. Although this allegation was somewhat imprecise, it was sufficient to apprise the Defendants of the nature of the charges against them. Further, in its Opposition to Defendants' Motion to Dismiss, the government represented that, at trial, it intended to prove that Defendants made misrepresentations to receive "increased" compensation, in the form of bonuses and other payments that were "tied to sales/revenue targets." [ECF No. 224], p. 52. This theory would have been consistent with McNally and subsequent First Circuit precedent, and the Defendants' motion to dismiss the wire fraud charge in Count 8 was therefore DENIED without prejudice. Had the government not dismissed Count 8 prior to trial, it would have been required to prove that the compensation, payments, and/or bonuses allegedly sought by Defendants were benefits to which they were not otherwise entitled, and that these benefits were to be obtained through the allegedly fraudulent scheme relating to the Stratus.

**iii. MTD 1, 2, 3, 6 and 7: Adulteration and Misbranding (Counts 9-18)**

The remaining motions to dismiss (MTD 1, 2, 3, 6 and 7) all raised various constitutional and statutory challenges to the misbranding and adulteration charges. Given that these issues will no doubt be re-visited in post-trial motion practice, the Court will say only the following: the motions raised a number of interesting and innovative legal arguments. For the most part, however, these motions challenged the legal viability of the charging theories rather than the sufficiency of the facts alleged in the Indictment. Given the standard applicable to pre-trial motions to dismiss, the Court deemed it more appropriate for these issues to be dealt with at trial, through jury instructions, or in post-trial motions. Therefore, Motions to Dismiss 1, 2, 3, 6, and 7 were all denied with leave to renew as appropriate.

## IV. CONCLUSION

For the foregoing reasons, (1) Defendants' Motions to Sever [ECF Nos. 214, 219] were DENIED without prejudice; (2) Defendants' Objections to the Magistrate Judge's Discovery Rulings [ECF Nos. 153, 154] were OVERRULED; and (3) Defendants' Motions to Dismiss [ECF Nos. 183, 184, 186, 187, 190, 193, 195] were DENIED without prejudice to renew as appropriate.

**SO ORDERED.**

Dated: August 22, 2016

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE